



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,292	03/21/2001	Borge Kringelum	030307- 0197	1783

22428 7590 11/15/2005

FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

DAVIS, RUTH A

ART UNIT	PAPER NUMBER
----------	--------------

1651

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/813,292	Applicant(s) KRINGELUM ET AL.	
	Examiner Ruth A. Davis	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's Request for Continued Examination, amendment and response filed September 28, 2005 has been received and entered into the case. Claim 28 is added. Claims 1 – 28 are pending and have been considered on the merits. All arguments and the declaration have been fully considered.

Claim Rejections - 35 USC § 112

Rejected under 35 U.S.C. 112, first paragraph, have been withdrawn due to amendment.

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 is rendered vague and indefinite for reciting "respectively", because it is unclear what is respective to what, since there are not multiple references in the claim.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1 – 7, 11, 17 – 22 and 24 – 27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Kosikowski.

Applicant claims a method for supplying a starter culture with a consistent quality at different propagation factories or plants, the method comprising:

- (i) providing an inoculum material comprising a concentrate of starter culture cells,
- (ii) allowing the starter culture to propagate,
- (iii) harvesting the cells to obtain a starter culture;

wherein step (i) comprises (a) concentrating the inoculum of step (i) to obtain a concentrated stock inoculum, (b) dividing the concentrated inoculum into subsets and providing the subsets to

Art Unit: 1651

different factories/plants, each having a quality to inoculate a medium at different factories/plants, (c) inoculating the mediums at different locations with the subset directly into the medium;

and wherein when steps (ii) – (iii) are repeated with the another subset of the stock at different factories/plants, the starter cultures have a consistent quality.

The inoculum material of step (i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium, the concentrated inoculum of step (a) is at least 10^8 CFU/gram. The subset inoculum material of step (c) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (c) contains at least 10^5 CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriaceae, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (ii) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives.

Art Unit: 1651

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least 10^9 CFU/g to a culture medium, growing the cells resulting in a medium with at least 10^7 CFU/g, propagating the cells to produce a starter culture with 10^9 CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include *Lactococcus* (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to concentrate and/or divide the inoculum into subsets as a matter of routine practice and procedure. In support, Kosikowski et al. (US 5098721) teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures are used as a bulk starter (or starter culture) (col.1). Kosikowski additionally teaches the mother culture can be concentrated for storage (col.1) prior to division and inoculation.

The references do not teach the method wherein the subsets are provided to different factories and/or plants. However, the location of where the actual steps take place do not patentably distinguish the method from the prior art, since practicing the methods at different locations would not materially change the culture method. Absent evidence that practicing the method in different propagation factories and/or plants would materially change the method steps from those in the prior art, the claims are rendered obvious.

Art Unit: 1651

Sing does not teach each of the claimed “quantities sufficient”, rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

6. Claims 1 – 7, 11, 17 – 22 and 24 – 27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Kosikowski and Czulak.

Applicant claims a method for supplying a starter culture with a consistent quality at different propagation factories or plants, the method comprising:

- (i) providing an inoculum material comprising a concentrate of starter culture cells,
- (ii) allowing the starter culture to propagate,
- (iii) harvesting the cells to obtain a starter culture;

wherein step (i) comprises (a) concentrating the inoculum of step (i) to obtain a concentrated stock inoculum, (b) dividing the concentrated inoculum into subsets and providing the subsets to different factories/plants, each having a quality to inoculate a medium at different locations, (c) inoculating the mediums at different factories/plants with the subset directly into the medium;

and wherein when steps (ii) – (iii) are repeated with the another subset of the stock at different factories/plants, the starter cultures have a consistent quality.

Art Unit: 1651

The inoculum material of step (i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium, the concentrated inoculum of step (a) is at least 10^8 CFU/gram. The subset inoculum material of step (c) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (c) contains at least 10^5 CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriaceae, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (ii) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least 10^9 CFU/g to a culture medium, growing the cells resulting in a medium with at least 10^7 CFU/g, propagating the cells to produce a starter culture with 10^9 CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are

Art Unit: 1651

named to include *Lactococcus* (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to concentrate and/or divide the inoculum into subsets as a matter of routine practice and procedure. In support, Kosikowski et al. (US 5098721) teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures are used as a bulk starter (or starter culture) (col.1).

Kosikowski additionally teaches the mother culture can be concentrated for storage (col.1) prior to division and inoculation.

The references do not teach the method wherein the subsets are provided to different factories and/or plants. However, the location of where the actual steps take place do not patentably distinguish the method from the prior art, since practicing the methods at different locations would not materially change the culture method. Absent evidence that practicing the method in different propagation factories and/or plants would materially change the method steps from those in the prior art, the claims are rendered obvious.

Sing does not teach the culture medium comprising skimmed milk. However, Czulak teaches a method of inoculating milk with a fat content of 0.3 – 1.5% (part skim and low fat milk) to produce cheese (abstract). Czulak teaches that use of skim milk enables a cheese product to be made with a substantially reduced fat content (col.1 line 10-15). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Czulak to use a

Art Unit: 1651

culture medium including at least part skim milk in the method of Sing with a reasonable expectation of success for obtaining a dairy product with a reduced fat content.

The above references do not teach each of the claimed “quantities sufficient”, rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

7. Claims 1 – 11, 17 – 22 and 24 – 27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Kosikowski and Lizak.

Applicant claims a method for supplying a starter culture with a consistent quality at different factories/plants, the method comprising:

- (i) providing an inoculum material comprising a concentrate of starter culture cells,
- (ii) allowing the starter culture to propagate,
- (iii) harvesting the cells to obtain a starter culture;

wherein step (i) comprises (a) concentrating the inoculum of step (i) to obtain a concentrated stock inoculum, (b) dividing the concentrated inoculum into subsets and providing the subsets to different factories/plants, each having a quality to inoculate a medium at different locations, (c) inoculating the mediums at different factories/plants with the subset directly into the medium;

Art Unit: 1651

and wherein when steps (ii) – (iii) are repeated with the another subset of the stock at different factories/plants, the starter cultures have a consistent quality.

The inoculum material of step (i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium, the concentrated inoculum of step (a) is at least 10^8 CFU/gram. The subset inoculum material of step (c) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (c) contains at least 10^5 CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriaceae, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The stock inoculum material or subset is liquid, frozen, or dried; the frozen inoculums are first thawed before inoculation; and the subsets are combined with an aqueous medium to obtain a suspension before cultivating. The cells of step (ii) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least 10^9 CFU/g to a

Art Unit: 1651

culture medium, growing the cells resulting in a medium with at least 10^7 CFU/g, propagating the cells to produce a starter culture with 10^9 CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to concentrate and/or divide the inoculum into subsets as a matter of routine practice and procedure. In support, Kosikowski et al. (US 5098721) teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures are used as a bulk starter (or starter culture) (col.1).

Kosikowski additionally teaches the mother culture can be concentrated for storage (col.1) prior to division and inoculation.

The references do not teach the method wherein the subsets are provided to different factories and/or plants. However, the location of where the actual steps take place do not patentably distinguish the method from the prior art, since practicing the methods at different locations would not materially change the culture method. Absent evidence that practicing the method in different propagation factories and/or plants would materially change the method steps from those in the prior art, the claims are rendered obvious.

Sing does not teach the methods wherein the inoculums are liquid, frozen or dried; wherein a frozen inoculum is thawed and a dried subset is combined with an aqueous medium

Art Unit: 1651

before inoculating into the culture medium. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to do so as a matter of routine practice. In support, Lizak teaches conventional storage of starting cultures includes liquid culture, frozen culture and dried culture (col.6 line 53-59). Although Lizak does not specifically teach frozen cultures are thawed and dried cultures are suspended in a liquid medium before inoculation, it was well known in the art to do so at the time of the invention. Therefore, at the time of the invention, one of ordinary skill in the art would have been motivated by conventional practice to obtain stock inoculum and/or subset cultures as a liquid, frozen or dried, thaw it and/or suspend the dried culture in a liquid medium because it was routine in the art as demonstrated by Lizak.

The references do not teach each of the claimed “quantities sufficient”, rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

8. Claims 1 – 7, 11 – 22 and 24 – 27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Kosikowski, Vanderbergh and Matsummiya.

Applicant claims a method for supplying a starter culture with a consistent quality at different factories/plants, the method comprising:

Art Unit: 1651

- (i) providing an inoculum material comprising a concentrate of starter culture cells,
- (ii) allowing the starter culture to propagate,
- (iii) harvesting the cells to obtain a starter culture;

wherein step (i) comprises (a) concentrating the inoculum of step (i) to obtain a concentrated stock inoculum, (b) dividing the concentrated inoculum into subsets and providing the subsets to different factories/plants, each having a quality to inoculate a medium at different factories/plants, (c) inoculating the mediums at different locations with the subset directly into the medium;

and wherein when steps (ii) – (iii) are repeated with the another subset of the stock at different factories/plants, the starter cultures have a consistent quality.

The inoculum material of step (i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium, the concentrated inoculum of step (a) is at least 10^8 CFU/gram. The subset inoculum material of step (c) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (c) contains at least 10^5 CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriaceae, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk

Art Unit: 1651

for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (ii) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives. The stock inoculum is supplied in a sealed enclosure, made from a flexible material selected from polyolefin, substituted olefin, copolymer of ethylene, polypropylene, polyethylene, polyester, polycarbonate, polyamide, acrylonitrile and a cellulose derivative; a metal foil; has a content of at least 0.01 liters; has an outlet for connecting to the culture medium container, which allows for aseptic inoculation.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least 10^9 CFU/g to a culture medium, growing the cells resulting in a medium with at least 10^7 CFU/g, propagating the cells to produce a starter culture with 10^9 CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to concentrate and/or divide the inoculum into subsets as a matter of routine practice and procedure. In support, Kosikowski et al. (US 5098721) teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures are used as a bulk starter (or starter culture) (col.1).

Art Unit: 1651

Kosikowski additionally teaches the mother culture can be concentrated for storage (col.1) prior to division and inoculation.

The references do not teach the method wherein the subsets are provided to different factories and/or plants. However, the location of where the actual steps take place do not patentably distinguish the method from the prior art, since practicing the methods at different locations would not materially change the culture method. Absent evidence that practicing the method in different propagation factories and/or plants would materially change the method steps from those in the prior art, the claims are rendered obvious.

Sing does not teach that the stock inoculum is provided in a sealed enclosure as claimed. However, Vandenberg teaches starter cultures can be stored in leak-proof containers such as a plastic bag, plastic container, metal foil, or sealable containers (col.4 line 30-40). While Vandengergh does not teach the material used or size of such containers, Matsumiya discloses cell culture containers made from ethylene copolymers, polyethylene, polypropylene, acrylonitrile copolymers (col.1 line 30-37). In addition, Matsumiya teaches that the flexible, bag like structures have an inlet tube and an outlet tube with a coupler at its end (col.1 line 23-30). At the time of the claimed invention, one of ordinary skill in the art would have been motivated to provide a stock inoculum in a sealed enclosure because it was well known in the art to do so as demonstrated by Vandengergh and Matsumiya. Furthermore, it would have been well within the purview of one of ordinary skill in the art to optimize the capacity of such containers to correspond with volume of the culture as a matter of routine practice.

The references do not teach each of the claimed “quantities sufficient”, rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have

Art Unit: 1651

been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

9. Claims 1 – 7, 11, 17 – 22 and 24 – 27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Kosikowski, Czulak and Lizak.

Applicant claims a method for supplying a starter culture with a consistent quality at different factories/plants, the method comprising:

- (i) providing an inoculum material comprising a concentrate of starter culture cells,
- (ii) allowing the starter culture to propagate,
- (iii) harvesting the cells to obtain a starter culture;

wherein step (i) comprises (a) concentrating the inoculum of step (i) to obtain a concentrated stock inoculum, (b) dividing the concentrated inoculum into subsets and providing the subsets to different factories/plants, each having a quality to inoculate a medium at different factories/plants, (c) inoculating the mediums at different locations with the subset directly into the medium;

and wherein when steps (ii) – (iii) are repeated with the another subset of the stock at different factories/plants, the starter cultures have a consistent quality.

The inoculum material of step (i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium, the concentrated inoculum of step (a) is at least 10^8 CFU/gram. The subset

Art Unit: 1651

inoculum material of step (c) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (c) contains at least 10^5 CFU/g, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriaceae, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (ii) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least 10^9 CFU/g to a culture medium, growing the cells resulting in a medium with at least 10^7 CFU/g, propagating the cells to produce a starter culture with 10^9 CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Art Unit: 1651

Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to concentrate and/or divide the inoculum into subsets as a matter of routine practice and procedure. In support, Kosikowski et al. (US 5098721) teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures are used as a bulk starter (or starter culture) (col.1). Kosikowski additionally teaches the mother culture can be concentrated for storage (col.1) prior to division and inoculation.

The references do not teach the method wherein the subsets are provided to different factories and/or plants. However, the location of where the actual steps take place do not patentably distinguish the method from the prior art, since practicing the methods at different locations would not materially change the culture method. Absent evidence that practicing the method in different propagation factories and/or plants would materially change the method steps from those in the prior art, the claims are rendered obvious.

Sing does not teach each of the claimed “quantities sufficient”, rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

Art Unit: 1651

Sing does not teach the method wherein each of the named organisms are used.

However, at the time of the claimed invention, each of the claimed organisms were well known and used in the art as sources of starter cultures. In support, Czulak teaches a method of inoculating milk with *Lactobacillus* and *Streptococcus* cultures whereby the cultures produce a desired cheese flavor (abstract). In further support, Lizak teaches starter cultures of fungus, *Bacillus*, combinations thereof and yeasts genetically altered to express enzymes (col.6 line 10-21). Therefore, at the time of the invention, one of ordinary skill in the art would have been motivated by routine practice to use the above named microorganisms in the method of Sing with a reasonable expectation of successfully obtaining a starter culture.

10. Claims 1 – 7, 11 and 17 – 27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Koskowski, Rimler and Lizak.

Applicant claims a method for supplying a starter culture with a consistent quality at different factories/plants, the method comprising:

- (i) providing an inoculum material comprising a concentrate of starter culture cells,
- (ii) allowing the starter culture to propagate,
- (iii) harvesting the cells to obtain a starter culture;

wherein step (i) comprises (a) concentrating the inoculum of step (i) to obtain a concentrated stock inoculum, (b) dividing the concentrated inoculum into subsets and providing the subsets to different factories/plants, each having a quality to inoculate a medium at different factories/plants, (c) inoculating the mediums at different locations with the subset directly into the medium;

Art Unit: 1651

and wherein when steps (ii) – (iii) are repeated with the another subset of the stock at different factories/plants, the starter cultures have a consistent quality.

The inoculum material of step (i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium, the concentrated inoculum of step (a) is at least 10^8 CFU/gram. The subset inoculum material of step (c) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (c) contains at least 10^5 CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriaceae, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (ii) express desired gene products such as enzymes, active substances, polysaccharides or amino acids; or produce desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least 10^9 CFU/g to a

Art Unit: 1651

culture medium, growing the cells resulting in a medium with at least 10^7 CFU/g, propagating the cells to produce a starter culture with 10^9 CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to concentrate and/or divide the inoculum into subsets as a matter of routine practice and procedure. In support, Kosikowski et al. (US 5098721) teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures are used as a bulk starter (or starter culture) (col.1).

Kosikowski additionally teaches the mother culture can be concentrated for storage (col.1) prior to division and inoculation.

The references do not teach the method wherein the subsets are provided to different factories and/or plants. However, the location of where the actual steps take place do not patentably distinguish the method from the prior art, since practicing the methods at different locations would not materially change the culture method. Absent evidence that practicing the method in different propagation factories and/or plants would materially change the method steps from those in the prior art, the claims are rendered obvious.

Sing does not teach each of the claimed “quantities sufficient”, rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within

Art Unit: 1651

the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

Sing does not teach the method wherein the starter cells are used in the pharmaceutical industry and express a desired gene product such as an enzyme, pharmaceutically active substance, polysaccharide or amino acid. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to do so because it was a well known practice in the art at the time the invention was made. In support, Rimler teaches a method of propagating starter cells of *Haemophilus* in order to obtain products useful as immunological agents (abstract). Stock cultures of the bacteria are passed twice (or propagated, sub-cultured and propagated), cultured in a medium, inoculated into a starter culture tube and propagated (col.3 line 1-15) to obtain the desired pharmaceutically active substance. In further support, Lizak teaches starter cultures of fungus, *Bacillus*, combinations thereof and yeasts genetically altered to express enzymes (col.6 line 10-21). Moreover, at the time of the invention, one of ordinary skill in the art would have been motivated by conventional practice to obtain a desired gene product via the methods of Sing.

Response to Arguments

Applicant argues that Sing does not teach concentrating, dividing and shipping the subsets to different propagation factories or plants, that Sing requires diluting the inoculum then growing the culture before inoculating into milk products, which is a two step process and that a distinction of different locales is not immaterial, since it results in cultures with consistent qualities. Applicant additionally argues that Kosikowski teaches a 2 step selection, which implies that the quality is not consistent, and thus teaches away from shipping to other, different locations. Finally, applicant argues that Lizak does not teach thawing frozen inoculums or suspending dried cultures in liquid before directly inoculating the culture mediums and requests proof that it was known to do this in the art.

However, these arguments fail to persuade because sing specifically teaches growing the cells to a higher concentration followed by dividing the cells by inoculating into milk products (abstract). Furthermore, the claims do not require a shipping step thus this argument is not commensurate with the claims. Regarding the argument that Sing requires diluting and culturing the cells prior to inoculation, it is noted that the claims also require cells to be divided and cultured before inoculating as well. Regarding applicant's assertion that the location of the inoculation step is material to the invention, it is maintained that the location of where the actual steps take place do not patentably distinguish the method from the prior art, since practicing the methods at different locations would not materially change the culture method. Absent evidence that practicing the method in "different locations" would materially change the method steps from those in the prior art, the claims are rendered obvious. Applicant has not provided any evidence that the resulting culture is any different than those of the prior art.

Art Unit: 1651

Regarding applicant's assertion relative to Kosikowski, the reference is relied upon to demonstrate that it was known in the art to divide inoculums into subsets. It could be further implied that such subsets could be shipped to other locations, contrary to what applicant argues, since the subsets are used as starter cultures, as claimed.

Finally, regarding applicant's comments to Lizak, the reference itself is evidence that such steps were routinely practiced in the art. In addition, it is noted that the above statement that it was well known in the art to thaw frozen cultures or suspend dried cultures in liquid mediums before inoculation, was made in each and every action without traverse by applicant. Specifically, the actions mailed on June 28, 2004, November 5, 2003, April 8, 2003, July 19, 2002 and December 18, 2001. Since applicant has not traversed these statements previously, it is taken as admitted prior art.

It is noted that applicant does not address or traverse the final three rejections, thus these rejections are maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); alt. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis
November 8, 2005
AU 1651

A handwritten signature in black ink, appearing to read "R Davis", is positioned to the right of the typed name and date.